

Appl. No. 10/604,227

Attorney's Docket No. PC702,08 / 31132.164

REMARKS

Claims 1 and 3-21 were pending in this application. Claims 22-30 have been added. Thus, claims 1 and 3-30 are currently pending. Reconsideration of this application in light of the above amendments and the following remarks is requested.

Rejections under 35 U.S.C. §112

Claim 1

Claim 1 was rejected under 35 U.S.C. §112, first paragraph, for having a non-enabling disclosure and failure to comply with the written description requirement. Claim 1 was also rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. Claim 1 has been amended to include an indication surface.

Accordingly, Applicants respectfully request that the Examiner withdraw the §112 rejection of claim 1.

Rejections under 35 U.S.C. §102

Claim 1

Claim 1 recites:

An insertion device trajectory system for use with an insertion device in treating a patient, comprising:

- an energy source for producing an energy path in a direction away from the patient;
- an indication surface for indicating a trajectory of the energy path, thereby indicating any trajectory correction required for the insertion device; and
- a mechanism by which the energy source can be attached to the insertion device.

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by each of U.S. Patent No. 4,657,012 to Burgin ("Burgin") and U.S. Patent No. 6,428,180 to Karram ("Karram").

The PTO provides in MPEP §2131 that

"[t]o anticipate a claim, the reference must teach every element of the claim...."

Therefore, to sustain this rejection with respect to claim 1, each of Burgin and Karram must contain all of the above claimed elements of the claim. However, as shown below Burgin and Karram do not contain all of the claimed elements of claim 1.

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The most recent Office Action again asserts that "both Burgin and Karram teach insertion devices that illuminate the area at which the devices make contact. Once the user illuminates an area, it is clear whether the area illuminated is the correct insertion area or not. If the area illuminated by the device is not the correct insertion site the user may move the device to another location, therefore using the devices to indicate a required trajectory correction." Applicants respectfully disagree that this approach indicates any trajectory correction required for the device. Rather, such an approach would simply indicate, as noted by the Examiner, whether the illuminated area was the correct insertion site, not whether the trajectory of the device should be changed.

Regardless of the above argument, neither Burgin nor Karram disclose "producing an energy path away from the patient" as required by amended claim 1. Thus, neither Burgin or Karram teach all of the elements of claim 1.

Thus, the §102(b) rejection of claim 1 is not supported by either of the Burgin or Karram references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 1.

Claims 3-9, 11, and 12

Claims 3-9, 11, and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by either Burgin or Karram. However, as demonstrated above neither Burgin nor Karram contain all of the claimed elements of claim 1. Claims 3-9, 11, and 12 depend from and further limit claim 1. Therefore, the §102(b) rejection of claims 3-9, 11, and 12 is not supported by the Burgin or Karram references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 3-9, 11, and 12.

Claim 13

Claim 13 recites:

A medical alignment device for use with an instrument in treating a patient, comprising:
an energy source located on the instrument wherein the energy source produces an energy path away from the patient;
a reflecting element for reflecting the energy path; and
a surface for indicating the proximity of the reflected energy path to the energy source to indicate any alignment correction required for the instrument.

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Claim 13 was rejected under 35 U.S.C. §102(b) as being anticipated by each of Burgin and Karram. Therefore, to sustain this rejection with respect to claim 13, each of Burgin and Karram must contain all of the above claimed elements of the claim. However, as shown below Burgin and Karram do not contain all of the claimed elements of claim 13.

Again, as described in more detail with respect to claim 1, Applicants respectfully disagree that the approaches used in Burgin and Karram will indicate any trajectory correction required for a device. Rather, as noted by the Examiner, the approach used in these references would simply indicate whether the illuminated area was the correct insertion site, not whether the trajectory of the device should be changed.

However, regardless of the above argument, neither Burgin nor Karram disclose "the energy source produces an energy path away from the patient" as required by amended claim 13. Thus, neither Burgin or Karram teach all of the elements of claim 13.

Thus, the §102(b) rejection of claim 13 is not supported by either of the Burgin or Karram references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 13.

Claims 14-16

Claims 14-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Burgin. However, claims 14-16 depend from and further limit claim 13. Therefore, the §102(b) rejection of claims 14-16 is not supported by the Burgin reference, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 14-16.

Claim 18

Claim 18 recites:

A method of aligning a medical instrument used in treating a patient, the method comprising:

- generating an energy path from an energy source located on the medical instrument, the energy path directed away from the patient; and
- reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Claim 18 was rejected under 35 U.S.C. §102(b) as being anticipated by each of Burgin and U.S. Patent No. 5,647,373 to Paltieli ("Paltieli").

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Therefore, to sustain this rejection with respect to claim 18, each of Burgin and Paltieli must contain all of the above claimed elements of the claim. However, Burgin and Paltieli do not contain all of the claimed elements of amended claim 18. Specifically, neither Burgin nor Paltieli disclose generating an "energy path directed away from the patient."

Thus, the §102(b) rejection of claim 18 is not supported by either of the Burgin or Paltieli references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 18.

Claims 19-21

Claims 19-21 were also rejected under 35 U.S.C. §102(b) as being anticipated by Burgin and Paltieli. However, claims 19-21 depend from and further limit claim 18. Therefore, the §102(b) rejection of claims 19-21 is not supported by either of the Burgin or Paltieli references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 19-21.

Rejections Under 35 U.S.C. §103

Claim 10

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Karram in view of U.S. Patent No. 3,628,523 to Pirtle ("Pirtle"). Applicant traverses this rejection on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claim 10.

As the PTO recognizes in MPEP § 2142:

... The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the Examiner does not produce a prima facie case, the Applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that, in the present case, the Examiner has not factually supported a *prima facie* case of obviousness for the following mutually exclusive reasons.

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1. Even when combined, the references do not teach the claimed subject matter
As provided in 35 U.S.C. §103:

A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ... (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. Examiner asserts that Karram discloses all aspects of claims 1 and 9. However, as illustrated above, Karram does not disclose all aspects of claim 1 or claim 9. Again, Applicants respectfully disagree that the approach disclosed in Karram indicates any trajectory correction required for the device. Rather, such an approach simply indicates whether the illuminated area is the correct insertion site, not whether the trajectory of the device should be changed. Regardless, neither Karram nor Pirtle disclose "producing an energy path away from the patient" as required by claim 1, which claim 10 depends from and further limits.

Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 10. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 10 under 35 U.S.C. §103(a).

2. The combination of references is improper

There is still another mutually exclusive and compelling reason why Karram and Pirtle cannot be applied to reject claim 10 under 35 U.S.C. §103(a). The MPEP provides in §2142 that:

...the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.....The Examiner must put aside knowledge of the Applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.

Here, neither Karram nor Pirtle teaches, or even suggests, the desirability of the combination since neither teaches reflecting an energy path to indicate trajectory corrections required for the insertion device nor teaches producing an energy path away from the patient as recited in claim 1, which claim 10 depends from and further limits.

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Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 10.

In this context, the MPEP further provides at §2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that, absent some teaching, suggestion or incentive supporting combination, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention. In the present case, it is clear that the Examiner's combination arises solely from hindsight based on the invention and without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 10. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 10. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 10 under 35 U.S.C. §103(a).

Claims 13 and 17

Claim 13 recites:

A medical alignment device for use with an instrument in treating a patient, comprising:
an energy source located on the instrument wherein the energy source produces an energy path away from the patient;
a reflecting element for reflecting the energy path; and
a surface for indicating the proximity of the reflected energy path to the energy source to indicate any alignment correction required for the instrument.

Claims 13 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,598,269 to Kitaevich ("Kitaevich") in view of U.S. Patent No. 5,957,933 to Yanof ("Yanof"). Applicant traverses these rejections on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claim 13 and, therefore, claim 17 for the following mutually exclusive reasons.

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1. Even when combined, the references do not teach the claimed subject matter

As described above, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, neither Kitaevich nor Yanof teach producing an energy path away from the patient. Rather, both Kitaevich and Yanof teach producing a laser beam towards the patient. As both of these features—located adjacent to the insertion device and producing an energy path away from the patient—are requirements of claim 13, it is impossible to render obvious the subject matter of claim 13, as a whole, and the explicit terms of §103 cannot be met.

Thus, for these mutually exclusive reasons, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 13. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 13 under 35 U.S.C. §103(a).

Further, since claim 17 depends from and further limits claim 13 the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 17 either. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 17 under 35 U.S.C. §103(a) as well.

2. The combination of references is improper

There is still another mutually exclusive and compelling reason why Kitaevich and Yanof cannot be applied to reject claim 13 under 35 U.S.C. §103(a). That is, neither Kitaevich nor Yanof teaches, or even suggests, the desirability of the combination since neither teaches producing an energy path away from the patient, as specified above and as recited in claim 13. Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 13.

In this context, the courts have repeatedly held that, absent some teaching, suggestion or incentive supporting combination, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention. In the present case, it is clear that the Examiner's combination arises solely from hindsight based on the invention and without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 13. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 13. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 13 under 35 U.S.C. §103(a).

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Since claim 17 depends from and further limits claim 13 the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 17. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 17 under 35 U.S.C. §103(a) as well.

Conclusion

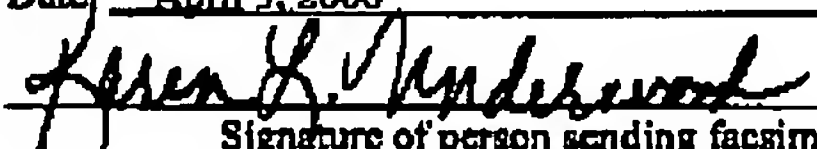
It is clear from all of the foregoing that independent claims 1, 13, 18, and 22 are in condition for allowance. Dependent claims 3-12, 14-17, 19-21, and 23-30 depend from and further limit the independent claims and therefore are allowable as well. An early formal notice of allowance of claims 1 and 3-30 is requested.

Respectfully submitted,


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